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10/667,655	09/23/2003	Nyle S. Elliott	A-8601	9116

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HOFFMAN, WASSON & GITLER, P.C.
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EXAMINER

MARCETICH, ADAM M

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/667,655

Applicant(s)

ELLIOTT, NYLE S.

Examiner

Adam Marcetich

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 13-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/23/2003, 9/23/2003, 12/17/03, 9/17/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12, drawn to an alert device for detecting the presence of fecal matter within a colostomy, classified in class 604, subclass 277.
 - II. Claims 13-20, drawn to a method of detecting the presence of fecal matter in a stoma, classified in class 604, subclass 318.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case (1) the process of indicating the presence of fecal material within a colostomy can be practiced with infrared light means, as utilized by Fisher (US Patent 4,813,422). (2) Also, the product as claimed can be used for another use such as indicating the flow through a lumen, such as for a manufacturing process requiring detection of material flow.
3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Mr. Christopher J. McDonald on 12 January 2007, a provisional election was made without traverse to prosecute the invention of invention I, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

6. The information disclosure statements (IDS) submitted on 19 December 2003 and 19 September 2005 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

7. The abstract of the disclosure is objected to for the following reasons:

8. In paragraph [0011], the language "An inflatable cuff about the tube" lacks antecedent basis since a tube is mentioned nowhere in the preceding disclosure.

9. In paragraph [0019], the language "the circuit board" lacks antecedent basis since a circuit board is mentioned nowhere in the preceding disclosure.
10. In paragraph [0021], the language "the lower ring 82 makes contact with the lower ring 82" should be changed to "the lower ring 82 makes contact with the lower ring 22" to agree with the drawings.
11. In paragraph [0022], the language "hydrophilic filter 82" should be changed to "hydrophilic filter 84" to agree with the drawings.
12. Correction is required. See MPEP § 608.01(b).

Claim Objections

13. Claims 1, 6, 10, 12, 15, 16 and 18 are objected to because of the following informalities:
 14. Regarding claim 1, the language "the stoma" and "said tube" lack antecedent basis within the claim.
 15. Regarding claim 6, the language "said engagement means" lacks antecedent basis with respect to claim 1.
 16. Regarding claim 10, the language "said tube" lacks antecedent basis with respect to claim 1.
 17. Regarding claim 13, the language "attaching said port member to the body" should be changed to language removing the body from the scope of the invention. Also, the language "depending into the stoma" is unclear and should be changed to more definite language.

18. Regarding claim 15, the language "wherein the alarm is visible" should be changed to "wherein the alarm is a visible signal" for clarity.
19. Regarding claim 16, the language "wherein the alarm is audible" should be changed to "wherein the alarm is an audible signal" for clarity.
20. Regarding claim 18, the language "wherein the port is attached" should be changed to language removing the body from the scope of the invention.
21. Appropriate correction is required.

Claim Rejections - 35 USC § 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

23. Claims 1, 2, 4, 5, 7-9 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Brady (US Patent 6,723,040).
24. Regarding claim 1, Brady discloses a bowel control probe (abstract) with a tubular body aligned with the anus (column 6, lines 23-24). Brady further discloses an alarm (column 2, lines 53-55) and an aperture with electrical conductors (column 2, lines 50-53). Brady also discloses a tubular plug with a lumen (Fig. 1, element 18 and

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column 4, lines 10-12), first and second conductive sensor rings (Fig. 1, elements 40 and 42 respectively), and third conductor (Fig. 1, element 46). It is an inherent property of electrical circuits for conductors to be in electrical connection. Therefore, second and third conductors 42 and 46 must be in electrical connection for the alarm circuit to function.

25. Regarding claim 2, Brady discloses an audible alarm (column 2, lines 53-55).

26. Regarding claim 4, Brady discloses a vibratory alarm (column 7, lines 25-29).

27. Regarding claim 5, Brady discloses transmitting an alarm signal to a remote location (column 7, lines 12-18).

28. Regarding claim 7, Brady discloses a flexible material composing the tubular body (column 4, lines 12-18).

29. Regarding claim 8, Brady discloses an inflatable cuff encircling the plug (column 3, lines 1-8 and Fig. 1, element 60).

30. Regarding claim 9, Brady discloses a pair of spaced-apart conductive rings (column 4, lines 58-62 and Fig. 1, elements 40 and 42).

31. Regarding claim 11, Brady discloses a charcoal filter (column 2, lines 63-64).

Claim Rejections - 35 USC § 103

32. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

33. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

34. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brady in view of Millot (US Patent 6,171,289). Brady lacks a visible alarm. Millot discloses a colostomy safety device (abstract) for the purpose of alerting a patient to the likelihood of detachment of a colostomy bag, with a visible alarm including an LED indicator (column 2, lines 65-68 and column 3, lines 1-4). Millot solves the problem of alerting a patient to the condition of a colostomy bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Brady as discussed with the visual alarm of Milliot in order to provide an alternate alert mechanism for the patient.

35. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brady in view of McDonnell (US Patent 4121589). Brady lacks threads as an engagement means. McDonnell discloses threads for the purpose of engaging the ostomy appliance (column 4, lines 4-7 and Fig. 1, element 7). McDonnell solves the problem of attaching an ostomy appliance to an implant adapted to engage a stoma. Therefore, it would have

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been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Brady as discussed with the threading of McDonnell in order to provide an engagement means between the colostomy device and patient.

36. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brady in view of Ballan et al. (US Patent 4,981,465). Brady lacks an absorbent sleeve around the tube. Ballan discloses a disposable closure for an artificial or natural anal opening, having a hydrophobic or swellable absorbent outer layer surrounding a non-absorbent core (column 11, lines 4-11 and Fig. 12, elements 74 and 72). Ballan solves the problem of controlling the movement of wastes from an artificial or incontinent natural intestinal opening (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Brady as claimed with the absorbent sleeve of Ballan in order to contribute to the stability of the probe within the anus due to the expansion of the material (column 3, lines 62-68). Another motivation is to provide a hydrophilic, biocompatible interface between the intestinal wall and the alert device.

37. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brady in view of Nielsen et al. (US Patent 6,764,474). Brady lacks an adhesive ring. Nielsen discloses an adhesive ring for the purpose of adhering an ostomy bag to a patient (column 6, lines 48-60 and Figs. 3, 4, element 21). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine

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the invention of Brady as discussed with the adhesive ring of Nielsen in order to provide sealing of an ostomy bag to the stoma of a patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:30am to 5:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Marcetich
Examiner
Art Unit 3761



AMM 1/17/07

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

